

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION

PAMELA S. SILVEY, et al.,	)	CASE NO. C-1-01-164
	)	
Plaintiffs,	)	JUDGE HERMAN J. WEBER
	)	
v.	)	MAGISTRATE JUDGE TIMOTHY S. BLACK
	)	
SMITHKLINE BEECHAM CORP.,	)	<b><u>DEFENDANT'S BRIEF IN OPPOSITION TO</u></b>
	)	<b><u>PLAINTIFFS' MOTION TO QUASH</u></b>
Defendant.	)	<b><u>SUBPOENA</u></b>
	)	
	)	(EXPEDITED ORAL ARGUMENT REQUESTED)
	)	
	)	

Defendant SmithKline Beecham Corp. ("SmithKline") submits its Brief in Opposition to Plaintiffs' Motion to Quash Subpoena. The subpoena in question should *not* be quashed because: (1) this subpoena was only issued as a last resort, after plaintiffs' counsel *agreed* to provide authorizations so that the documents could be procured, then ignored numerous follow-up requests for the documents in question, over a period of two years; (2) the subpoena requests *documents only*, not a personal appearance of anyone; (3) the subpoena is not burdensome because it was issued to the third party recipient's counsel, with advance notice and cooperation, and in a manner agreed upon by the subpoena recipient's counsel, so that the documents could be authenticated for use at trial; (4) plaintiffs have no standing to object to the subpoena as "burdensome," because it doesn't require *plaintiffs* to do anything; (5) the documents in question are clearly relevant, because they relate to a medical study analyzing the very claim at issue in this case – the cause of Ms. Silvey's

stroke; and (6) the MDL Court never issued any ruling limiting discovery of the *documents* in question. Finally, plaintiffs' technical challenges to the subpoena under Fed.R.Civ.Proc. 45 are being rendered moot by the reissuance of the subpoena by the undersigned counsel. (*See* Exhibit B.)

Quashing this subpoena would unfairly permit plaintiffs to benefit from their counsel's own refusal to answer reasonable and timely requests. This would greatly prejudice SmithKline by preventing procurement of relevant and important documents, despite SmithKline's diligent efforts to obtain those documents without burdening the Court. A memorandum of law and facts is attached. SmithKline also requests an expedited hearing to conduct oral argument on this issue, due to the urgent need for these documents with defendant's expert report deadline approaching on October 15, 2004.

Respectfully submitted,

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**MEMORANDUM OF LAW AND FACTS**

**I. STATEMENT OF FACTS**

**A. BACKGROUND FACTS**

This pharmaceutical product liability action was filed by plaintiffs Pamela and Kenneth Silvey in the United States District Court, Southern District of Ohio (Cincinnati) on March 19, 2001. There is one defendant -- SmithKline Beecham Corp. Plaintiffs claim that SmithKline's Contac® cold medicine caused her to have a stroke on January 15, 1998 – a claim which SmithKline vigorously refutes.

On September 27, 2001 this Court entered a stay of proceedings, and shortly thereafter this case was transferred to the United States District Court, Western District of Washington for multi-district litigation pretrial proceedings with Judge Barbara Jacobs Rothstein. (MDL No. 1407). The case was remanded back to this Court by an Order filed on March 16, 2004. Although fact discovery of this matter was essentially completed during the MDL, the subpoena in question was issued in order to authenticate documents to be used at trial (and to determine whether these documents are complete), not to re-open discovery.

The subpoena referenced in this brief was issued on September 3, 2004 to counsel for non-party Laura Sauerbeck, R.N., after advance discussion with Ms. Sauerbeck's counsel, wherein said counsel was advised that *only documents* were requested – no personal appearance being required. (*See Exhibit A.*) In order to render moot the procedural challenge to this subpoena noted in plaintiffs' Motion to Quash, this subpoena is being reissued forthwith in the format attached as Exhibit B. Ms. Sauerbeck participated in medical studies in 1998 in which plaintiff Pamela Silvey was a participant, and the subpoenaed documents were generated as a

result. The Cincinnati Court Reporter who served the subpoena on behalf of the undersigned counsel contemporaneously mailed a copy of the subpoena to plaintiffs' counsel, as a courtesy.

Plaintiffs electronically filed their Motion to Quash this subpoena on September 10, 2004. To date, no response to the subpoena has occurred. However, defense counsel is in urgent need of the documents in question, with defendant's expert report deadline approaching on October 15, 2004.

**B. THE SUBPOENA IN QUESTION WAS ONLY ISSUED AS A LAST RESORT AFTER PLAINTIFFS IGNORED DEFENDANT'S GOOD FAITH EFFORTS TO OBTAIN THE DOCUMENTS IN QUESTION.**

**1. SmithKline's First Attempt To Procure The Relevant Documents**

On *seven* separate occasions, plaintiffs have failed to respond to SmithKline's good faith requests for the very same documents now requested in the subpoena in question. First, as part of the MDL discovery proceedings, plaintiffs were required to disclose any and all medical personnel with whom she had any involvement relating to her stroke, and to produce any documents referencing such involvement. (*See* Exhibit C.) This mandatory disclosure, known as the Plaintiffs' Fact Statement ("PFS"), was to be served upon defendants, and to include signed medical authorizations permitting defendants to obtain all pertinent records.

Despite this PFS mandate, plaintiffs failed to disclose important documents and information that were required by the PFS and unquestionably relevant. Specifically, plaintiffs did not disclose: (1) that Pamela Silvey was involved in a medical study with Joseph Broderick, M.D. and was seen, examined and interviewed by Dr. Broderick's research nurse, Laura Sauerbeck, R.N., during the events in question, regarding the very issues at the core of this case (i.e. the cause of Mrs. Silvey's stroke); (2) plaintiffs also did not disclose the existence of questionnaires and other documents, generated through participation in these

Broderick/Sauerbeck studies, which compellingly show that Mrs. Silvey **never even used** defendant's product; (3) plaintiffs also did not disclose the fact that Ms. Silvey and her husband had participated in the "Yale Study" wherein the relation between PPA and stroke was investigated – a study which is central to plaintiffs' causation claim; and (4) plaintiffs also did not disclose the fact that Ms. Silvey and her husband also participated in *another study* by Dr. Broderick, investigating possible genetic and environmental causes of strokes. (These "genetic and environmental risk factor" study records are the subject of the subpoena at issue here.) This undisclosed "genetic and environmental risk factor" study ultimately concluded that persons with heavy smoking histories (such as Ms. Silvey) greatly increased their risk of stroke – a conclusion which undermines plaintiffs' causation claim in this lawsuit.

## **2. SmithKline's Second Attempt to Procure the Relevant Documents**

These key documents were again required to be produced by plaintiffs in response to the Deposition Notice *Duces Tecum* that preceded Ms. Silvey's deposition in December of 2002. (Exhibit D.) Again, plaintiffs ignored this reasonable discovery request, and produced zero documents at Ms. Silvey's deposition. It was only under cross-examination during the deposition itself that defendant discovered that Ms. Silvey may have been a participant in the medical studies noted above, wherein the cause of her stroke was investigated.

## **3. SmithKline's Third Attempt to Procure the Relevant Documents**

In the wake of Ms. Silvey's deposition, SmithKline's counsel wrote a letter to plaintiffs' counsel, dated January 13, 2003, requesting the medical study documents in question. (Exhibit E.) At this point, defense counsel still was not aware of exactly what documents were available, and in which studies Ms. Silvey had participated. In response to this request, plaintiffs did not produce *any* of the documents that are now requested by the subpoena in question.

#### **4. SmithKline's Fourth Attempt To Procure The Relevant Documents**

Again, on January 14, 2003, defense counsel wrote plaintiffs' counsel another letter demanding an updated disclosure of all pertinent documents, or signed authorizations so that defendant could procure those documents. (Exhibit F.) This letter also enclosed additional medical authorizations for Ms. Silvey to sign, and requested that these authorizations be executed and returned to defense counsel. In response to this request, plaintiffs *agreed* to sign and return authorizations, in a letter stating:

Thank you for your January 14, 2003 letter, wherein you requested additional medical authorizations and an updated version of Ms. Silvey's PFS. I indicated to you at the conclusion of Ken Silvey's deposition that I would be getting back with you soon regarding the additional medical authorizations. This letter will confirm that I have sent the authorizations to Ms. Silvey for her signature and are waiting for them to be returned to our office. Before I forward the medical authorizations to you, however, please kindly identify the additional medical care providers that you contend were not originally identified in Ms. Silvey's PFS.

(Letter from plaintiffs' counsel dated January 24, 2003, Exhibit G.)

#### **5. SmithKline's Fifth Attempt To Procure the Relevant Documents**

In response to plaintiffs' January 24 letter cited above, defense counsel again wrote to plaintiffs on February 17, 2003, once again requesting that the medical authorizations be provided, and specifically itemizing the deficiencies in plaintiffs' original PFS disclosure and requesting complete information. (Exhibit H.) In this letter, defense counsel again specifically demanded that plaintiffs produce authorizations enabling defendant to obtain the records of Dr. Broderick/Nurse Sauerbeck's medical studies involving plaintiff Pamela Silvey (which are the same documents requested in the subpoena in question). Both before and following this February 17, 2003 letter, defense counsel again contacted plaintiffs' counsel by phone and again

requested the medical authorizations in question, and updated PFS information. In response to these requests, plaintiffs stated that they would comply at least in part, but again produced nothing.

**6. SmithKline's Sixth Attempt To Procure The Relevant Documents**

With several months having passed, and no response from plaintiffs' counsel (despite plaintiffs' prior agreement to forward signed authorizations so the documents could be procured), SmithKline sent plaintiffs yet another letter, on October 1, 2003, again demanding signed medical authorizations, an updated PFS disclosure, and other long-overdue materials. (Exhibit I.) In this letter, defense counsel noted: "It would, of course, be our preference to work out this minor discovery dispute amicably rather than bothering Judge Rothstein again on this case." In response to this *sixth request* for the pertinent discovery, plaintiffs produced nothing.

**7. SmithKline's Seventh Attempt To Procure The Relevant Documents**

Finally, on October 21, 2003 defense counsel again demanded an updated PFS and signed authorizations, even enclosing yet another copy of the pertinent authorizations (including an authorization to obtain the same Dr. Broderick/Nurse Sauerbeck medical study documents requested in the subpoena). (Exhibit J.) Given plaintiffs' prior delays in responding to discovery, this letter specifically asked: "Please advise in writing if you anticipate any problem with responding to these discovery requests, so that, if necessary, I can promptly file a motion to compel (which I would prefer to avoid, if possible)." Anticipating the forthcoming remand from the MDL, this letter also noted: "... we would like to wrap up local discovery on this case by the end of the year at the latest." (Exhibit J.) Given plaintiffs' counsel's prior representation that authorizations *would be* forthcoming, defense counsel expected to receive the authorizations prior to remand. In response, plaintiffs again produced nothing.

To date, despite these *seven separate requests* for the records in question, plaintiffs have not responded, forcing defendants to issue the subpoena in question. Amazingly, plaintiffs now have the gall to move to quash this subpoena – a subpoena which was necessitated solely by plaintiffs' refusal to cooperate in discovery of this clearly relevant matter. Although defendant was ultimately able to procure many of the documents generated by Ms. Sauerbeck, additional documents apparently exist and must be authenticated for use at trial.

## **II. LAW AND ARGUMENT**

### **A. APPLICABLE LAW**

Federal Rule of Civil Procedure 26 provides "parties may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party." Fed.R.Civ.P. 26(b)(1). Relevant information "need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." *Id.*

The issuance of a subpoena is governed by Fed. R. Civ. P. 45. Section (c)(3)(A) of this rule provides:

On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it

- (i) fails to allow reasonable time for compliance;
- (ii) requires a person who is not a party or an officer of a party to travel to a place more than 100 miles from the place where that person resides, is employed or regularly transacts business in person, except that, subject to the provisions of clause (c)(3)(B)(iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held, or
- (iii) requires disclosure of privileged or other protected matter and no exception or waiver applies, or
- (iv) subjects a person to undue burden.



It is well-established that a motion to quash a subpoena is entrusted to the sound discretion of the court. *Fitch, Inc. v. UBS Painewebber, Inc.*, 330 F.3d 104, 108 (2d Cir.2003) (quoting *United States v. Sanders*, 211 F.3d 711, 720 (2d Cir.2000)). Whether a subpoena imposes an undue burden "depends upon such factors as relevance, the need of the party for the documents, the breadth of the document, the time period covered by it, the particularity with which the documents are described and the burden imposed." *Concord Boat Corp. v. Brunswick Corp.*, 169 F.R.D. 44, 49 (S.D.N.Y.1996) (quoting *United States v. IBM Corp.*, 83 F.R.D. 97, 104 (S.D.N.Y.1979)).

Under the circumstances in this case, plaintiffs have shown no basis to quash the subpoena in question, for the additional reasons set forth below.

**B. THE SUBPOENA IN QUESTION REQUESTS DOCUMENTS ONLY, NOT A PERSONAL APPEARANCE.**

Plaintiffs argue in their Motion to Quash that the subpoena should be quashed because it requires a deposition of a third party – Laura Sauerbeck, R.N. – who has already been deposed. This argument is without merit because the subpoena in question *does not require* the personal appearance of anyone, but rather simply the production of documents, as is customary with such subpoenas. The subpoena specifically states: "Documents may be sent to Tucker, Ellis & West, LLP, 1150 Huntington Building, 925 Euclid Avenue, Cleveland, Ohio 44115-1475 *in lieu of personal appearance*, ONLY if the documents contain a notarized certificate authenticating the documents." (Emphasis added.)(Exhibit A.) The reissued subpoena, Exhibit B, also clearly states that only documents are requested. (See Exhibit B.)

**C. THE SUBPOENA IS NOT BURDENSOME BECAUSE IT WAS ISSUED IN COOPERATION WITH THE RECIPIENT'S COUNSEL.**

Plaintiffs argue in their Motion to Quash that the subpoena was issued with inadequate notice and inadequate time to respond. This argument is also without merit. Counsel for the recipient (Nurse Sauerbeck) was contacted informally, well in advance of the issuance date for the subpoena, to provide advance notice as a courtesy, and to make sure that the recipient's counsel still represented Ms. Sauerbeck's interests. With regard to the *time to respond* provided in the subpoena, plaintiffs again attempt to take advantage of a time crunch that was created by plaintiffs' own refusal to permit fair discovery of the documents in question. If plaintiffs had appropriately responded to the *seven* previous good faith requests for the documents in question (as described above), there would be far less urgency to obtaining the documents at this late date, by subpoena. Moreover, the date for response to the subpoena was cleared with the recipient's counsel, and has already been extended such that the documents are probably ready to produce already.

**D. PLAINTIFFS HAVE NO STANDING TO OBJECT TO THE SUBPOENA IN QUESTION.**

The subpoena in question was issued to Laura Sauerbeck, R.N. (through her counsel). Ms. Sauerbeck is not a party to this lawsuit, nor is she officially affiliated with either party. However, she does have possession of clearly relevant medical study materials. To date, *Ms. Sauerbeck's counsel* has voiced no objection to the minimally-burdensome document request contemplated by the subpoena. Under these circumstances, plaintiffs have no standing to raise the subpoena challenges contained in plaintiffs' Motion to Quash. In fact, all of the objections raised by plaintiffs in their Motion to Quash (i.e. complaints about burden on the recipient, complaints about the time permitted to respond to the subpoena, and complaints about

technicalities of the subpoena issuance) are potential issues unique to the subpoena *recipient*, rather than the plaintiffs. Plaintiffs have raised no claim that the documents in question are privileged.

**E. THE DOCUMENTS IN QUESTION ARE CLEARLY RELEVANT, BECAUSE THEY RELATE TO A MEDICAL STUDY ANALYZING THE VERY CLAIM AT ISSUE IN THIS CASE.**

The subpoenas attached as Exhibits A & B request documents that are believed to include records from a medical study entitled *Genetic And Environmental Risk Factors For Hemorrhagic Stroke* – a study in which plaintiff Pamela Silvey actually participated. This issue of the “cause” of Ms. Silvey’s stroke is the precise issue which plaintiffs have raised with this lawsuit. Plaintiffs claim that use of defendant’s cold medicine caused her stroke – a claim that is extraordinarily weak and unsupported for numerous reasons. As part of that claim, plaintiffs must rule out other “genetic and environmental” explanations for Ms. Silvey’s stroke, including her admitted history of smoking 1.5 packs of cigarettes per day beginning at age 14. It is believed that the *Genetic And Environmental Risk Factors* study documents would support the assertion that Ms. Silvey’s substantial smoking history and pre-existing aneurysm were much more likely causes of her stroke, compared with any cold medicine.

Moreover, one need look no further than documents already obtained in this case from a *different study*, also conducted by Dr. Broderick and Ms. Sauerbeck, to see the potential relevancy of the documents now under subpoena. Plaintiff Pamela Silvey participated in *another study* known as the “Hemorrhagic Stroke Project,” (“HSP”) for which defense counsel already has procured Ms. Silvey’s study case files through discovery in the MDL. Contained in Ms. Silvey’s HSP case files were numerous documents showing that Ms. Silvey *did not use* defendant’s product during the relevant time period – even including detailed questionnaires

wherein Ms. Silvey and her husband *specifically deny* that she used defendant's cold medicine prior to her stroke. (Depo of Laura Sauerbeck, R.N., pp. 27, 33, 41, 43, 49-50, 52-53, 60, 78, Exhibit K.)

Finally, when Nurse Sauerbeck was deposed on March 13, 2003, she specifically admitted that she had contact with plaintiff Pamela Silvey in the context of the *Genetic And Environmental Risk Factors* study (i.e. the study documents requested in the subpoena in question) (Deposition of Laura Sauerbeck, R.N., taken March 13, 2003, at pp. 45-46, Exhibit K.) Hence, documents like those requested in the subpoena in question are clearly relevant and, in some cases, critically important to the central issues in this case.

**F. THE MDL COURT NEVER ISSUED ANY RULING LIMITING DISCOVERY OF THE DOCUMENTS IN QUESTION.**

Plaintiffs argue in their Motion to Quash that the MDL Court somehow ruled that the documents under subpoena were not discoverable. This argument is without merit. The MDL ruling which plaintiffs' counsel has apparently misconstrued occurred at the time of Ms. Sauerbeck's second deposition on March 13, 2003. This ruling had nothing whatsoever to do with document requests. Rather, this ruling (which was apparently not journalized due to its informality) was solely issued to lessen the *deposition time* burden on Ms. Sauerbeck, because she had previously been deposed as a "generic MDL witness" in numerous PPA cases. (Deposition of Laura Sauerbeck, R.N., taken March 13, 2003, at pp. 46, 78, Exhibit K.) In fact, the main reason why Ms. Sauerbeck had to be re-deposed was because plaintiffs failed to disclose her involvement in various Dr. Broderick/Ms. Sauerbeck studies *prior to* Ms. Sauerbeck's first deposition. Specifically, Judge Rothstein advised, in a conference call ruling shortly prior to Ms. Sauerbeck's deposition in the *Silvey* case, that the deposition questioning

should be limited to one hour, and should only include questioning about the HSP study – in order to save time. (*See id.*) At no point did this ruling set any limitation on document requests, especially documents which are clearly relevant, easily obtainable, and which Ms. Sauerbeck’s counsel has no objection to producing.

Moreover, the MDL Court has never proscribed the use of subpoenas upon remand to authenticate documents for trial. And, the Final MDL Pretrial Order specifically provides that updated records (and even case-specific depositions) may be conducted, *after* remand, upon a showing of good cause. (*See* Exhibit L.) Clearly, given the circumstances set forth above, “good cause” exists to enforce this subpoena. The Final MDL Pretrial Order also provides that case-specific discovery is now within the jurisdiction of this Court, and not, with respect, the MDL Court. (Exhibit L.) It would be more efficient for the recipient and her counsel to produce documents now, rather than await the potential uncertainties of responding to a subpoena during trial of this matter. Indeed, the cooperation at this time of Ms. Sauerbeck through her counsel so demonstrates. Plaintiffs apparently desire to keep the requested documents hidden through the trial of this action, even if that might inconvenience the subpoena recipient. That approach should be rejected, and plaintiffs’ motion should be denied.

**III. CONCLUSION**

For the foregoing reasons, defendant requests that the Court deny plaintiffs' motion. A Proposed Order denying plaintiffs' Motion to Quash and ordering that the documents in question be produced is attached hereto for the Court's convenience.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on this \_\_\_\_\_ day of September 2004, a copy of the foregoing Defendant's Brief In Opposition to Plaintiffs' Motion To Quash Subpoena (exhibits attached) was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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v.	)	MAGISTRATE JUDGE TIMOTHY S. BLACK
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SMITHKLINE BEECHAM CORP.,	)	<b><u>ORDER</u></b>
	)	
Defendant.	)	
	)	
	)	

Before the Court is plaintiffs' Motion to Quash Subpoena, For Protective Order, and For Sanctions, ("plaintiffs' Motion") which was filed on September 10, 2004. The Court has reviewed the briefs of the Parties and hereby DENIES plaintiffs' motion, and further orders that the subpoena be enforced, and the documents in question be produced by the subpoena recipient forthwith.

**IT IS SO ORDERED.**

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MAGISTRATE JUDGE TIMOTHY S. BLACK

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DATE